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Paper No. CB(2)1297/00-01(01)

Preclusion for blood donation based on sexual behaviours

– Information on practices adopted in selected countries –

1. This paper presents a summary of preclusion practices in blood donation in relation to persons who engage in specific types of sexual behaviours.

2. Blood transmission is one of the four major sources of HIV infection. To minimise infection through this source, many countries have adopted preclusion measures to reduce the possibility of collecting blood from the high-risk population. This preclusion stems from international concerns for blood safety.

3. Since the 1980s, blood collected is screened for the HIV virus in many countries. The 1980's also saw blood donation guidelines beginning to include certain types of high-risk sexual and intravenous behaviours in donor screening. It was considered that unprotected penetrative anal sex carried much greater risk of HIV infection than unprotected vaginal intercourse. Hence, male-to-male sex was considered high-risk sexual behaviour as it was likely to involve penetrative anal sex. Homosexual men were directly implicated and became a target group for preclusion in blood donation. It must be pointed out that anal sex is not uncommon in heterosexual or bisexual contact and the proper use of condom provide protection against infection.

4. The World Health Organization estimated that in 1997, between 5-10% of HIV cases worldwide were due to sexual transmission between men. These figures varied in different countries and were believed to be closer to 70% in US, Australia, New Zealand and most European countries.[1] Locally, as at September 2000, about

[1] UNAIDS Technical update, AIDS and men who have sex with men. May 2000.

20% of the total reported HIV/AIDS cases were believed to be due to homosexual contact, 5% to bisexual contact and 60% to heterosexual contact.[2]

5. It must be noted that there is a rising trend in HIV infection from heterosexual exposure. In Australia, the percentage of HIV/AIDS cases from heterosexual exposure rose from 5.6% in 1994 to 22.5% in 1999. In Canada, it rose from 11.6% in 1994 to 22.8% in 1999. In Hong Kong, the cumulative total of HIV/AIDS cases from heterosexual contact rose from 46.1% in 1996 to 58.9% in 2000. Correspondingly, transmission through homosexual contact has reduced to 19.5% and bisexual contact to about 5% from 28.3% and 9.3% respectively in 1996.[3]

6. In guidelines from blood donation bodies to donors, donors are advised of certain conditions that make them unsuitable for blood donation. Sexual behaviours are included in these conditions. Annex A provides details of preclusion practices in selected countries based on sexual behaviours.

7. As can be seen in Annex A, preclusion notwithstanding, the deferral period for men who have sex with men (MSM) varies from temporary to permanent. The shortest deferral period of one year is to be found in Australia and Japan. In most countries, the deferral period for sex workers is similar to MSM but is shorter for people who have sex with MSM or sex workers.

8. Some of these guidelines go further to prompt prospective donors to identify symptoms suggestive of HIV infection or AIDS. For example, in Australia, US and Singapore, prospective donors are prompted to consider whether they have any symptoms e.g. unexplained weight loss; swollen glands in the neck, armpits or groins; persistent diarrhoea or rare cancers, etc. which may indicate

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[2] Source: Quarterly HIV /AIDS Reported Statistics (Highlights of Quarter July-September 2000) prepared by the Virtual AIDS Office of Hong Kong, Department Health.

[3] Source: Quarterly HIV /AIDS Reported Statistics (Vol.2 No.2 April 1996) prepared by the Virtual AIDS Office of Hong Kong, Department Health.

HIV/AIDS infection.

9. In this regard, the Hong Kong Red Cross Blood Transfusion Service does not prompt prospective donors separately on these symptoms. Questions such as "In the past 4 weeks, have you had diarrhoea?" are included in the health enquiry registration forms for screening purposes, but donors are not informed of the significance of these questions with regard to possible HIV/AIDS infection.

10. The International Federation of Red Cross and Red Crescent Society (IFRC) recommends that governments and blood donation bodies should set up a national blood policy. Annex B provides examples of countries where preclusion is based either on statutory instruments or recommended guidelines. In Hong Kong, there are no regulations directly relating to blood donor recruitment. Self-deferral is encouraged through public education programmes. The Hospital Authority, however, has an Expert Panel of Blood and Blood Product Safety.

11. In US, the Food and Drug Administration (FDA) proposed in September 2000 to change the policy of lifetime deferral for MSM to a five-year deferral period on the grounds that new blood tests were more reliable and could track HIV infection quicker. The FDA's Blood Products Advisory Committee on a marginal vote of 7 to 6 rejected this because it felt there was insufficient evidence to support such a policy change.

12. In most countries, blood collected is tested for Hepatitis B and C, HIV and HTLV infection. Some blood donation agencies, such as the Australian Red Cross Blood Service, also include the Nucleic Acid Testing (NAT). NAT is known for its benefit of reducing the window period for detecting Hepatitis C and HIV virus. NAT is now used on a trial basis in Hong Kong.

13. Donor screening is still largely dependent on voluntary and honest

reporting by prospective donors. The "dishonesty", if any, is not necessary due to mischief, but rather, a lack of awareness, different perceptions and understanding of behaviour, or even forgetfulness. For these reasons, an effective prompting system and a good blood-screening test are equally important for the purpose of blood safety.

14. Blood collection agencies elsewhere have been held liable for claims where the system for reducing the risk of collecting HIV-tainted blood was not regarded as reasonable. The EOC recommends that donor screening be based on "objectively described" high-risk sexual behaviour and not "perceived" high-risk groups.

Equal Opportunities Commission
April 2001

Annex A

Deferral Period for Blood Donation based on Sexual Behaviours In Selected Countries

Blood Donation Body	Male-to-male sex		Paid sex		Others (sexual activity or condition)	
	Men who have had male-to-male sex (MSM)	Women who have had sex with MSM	Sex workers	Individuals who have had sex with a sex worker	Permanent Deferral	Temporary Deferral
Hong Kong Hong Kong Red Cross Blood Transfusion Service	Permanent	1 year	Permanent	1 year	– Sex partner is HIV positive – Sex with multiple partners	**1 Year** for those who have had sex with the following: – Person at risk of HIV infection – Person suspected to be HIV infected
China Shanghai Blood Center	Permanent[1]	Permanent[1]	Permanent	Permanent	– Homosexual and their spouses – Sex with multiple partners	
Taiwan Organization of the Chinese Blood Donation Association	Permanent[1]	(Not specified as a group for deferral)	Permanent	2 years	– Sex with multiple partners – Homosexuals and Bisexuals	**2 years** for those who have had sex with a stranger
Singapore Singapore Blood Transfusion Service	Permanent[2]	Permanent[2]	Permanent	Permanent	– Sex with multiple partners – Casual sex – Sex with someone who is at risk of HIV infection	
Japan Japan Red Cross Society	1 year	1 year	(Not specified as a group for deferral)	(Not specified as a group for deferral)	– Sex with unstable sex partners	
Australia Australian Red Cross Blood Service	1 year (Including sex with bisexual men)	1 year (Including sex with bisexual men)	1 year	1 year		

Blood Donation Body	Male-to-male sex		Paid sex		Others (sexual activity or condition)	
	Men who have had male-to-male sex (MSM)	Women who have had sex with MSM	Sex workers	Individuals who have had sex with a sex worker	Permanent Deferral	Temporary Deferral
New Zealand New Zealand Blood Service	10 years [3]	1 year	10 years	1 year		**1 year** for those who have had sex with someone who is at risk of HIV infection
US American Red Cross	Permanent[2]	Permanent[2]	Permanent[2]	1 year	– Sex with anyone who was born or lived in Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria since 1977.	**1 year** for those who: – Have been raped – Have had sex with someone who is at risk of HIV infection
Canada Canada Blood Services	Permanent[2]	Permanent[2]	Permanent[2]	Permanent[2]	– Sex with a person at risk of HIV infection	**1 year** for those who have had sexual contact with a person with hepatitis in the last year.
UK UK National Blood Service	Permanent[3]	1 year	Permanent	1 year		**1 year** for those who – Have had sex with someone who is at risk of HIV infection – Have been sexually active in Africa (apart from Morocco, Algeria, Libya, Tunisia or Egypt)

Notes:

[1] MSM is not specified as a group for deferral but since homosexual men are permanently deferred, MSM are likely to be treated the same.

[2] Applicable to those who have engaged in such sexual activity from 1977.

[3] Deferral period is applicable to MSM even if they claimed to practice safe sex by using condoms.

Annex B

Regulatory framework for blood donors selection

Examples in selected countries

Australia

Statutory instruments require donors to make a declaration in a prescribed form. For example, the Health (Infectious Diseases) (Donation Statement) Regulations 1999, made under the Health Act 1958, in the State of Victoria; the Blood Contaminants Act 1985 in South Australia; and the Blood Donation (Limitation of Liability) Act of 1985 in Western Australia. These declarations include a direct question on male-to-male sex.

Statutory instruments also impose penal sanctions on donors for false or misleading declarations. For example, the Human Tissue (Amendment) Act 1985 in New South Wales imposes a penalty of A$5,000 or one-year imprisonment, or both, for a false or misleading declaration.

US

The Food and Drug Administration (FDA) is the regulatory arm of the Public Health Service, responsible for the regulation of blood and blood products as well as the licensing and inspection of blood centers and blood product manufacturers. If regulations and licensing agreements were breached, the FDA could issue warning letters to suspend or revoke the license. Guidelines on blood safety are issued upon the recommendation of the FDA's Blood Products Advisory Committee. Although these guidelines do not have regulatory power, they are generally followed by most blood transfusion services in US.

The FDA's donor deferral policy in December 1984 deferred males who had had sex with more than one male (MSM) since 1979 from giving blood. In September 1985, MSM was redefined to include men who have had sex with another man, even once, since 1977. Guidelines to blood establishments recommend asking direct questions concerning risk behaviours for HIV infection but not requiring written statement from prospective donors.

UK

There is no regulatory control on blood donor selection although all regional transfusion centers in the UK are required to adhere to guidelines issued by the Department of Health (formerly the Department of Health and Social Security before 1988). The Department regularly issues leaflets on AIDS and blood donation to emphasize screening of donors, but transfusion services do not require prospective donors to make a written or oral declaration that they had not been at risk of contracting HIV.

Canada

There are no direct regulations on collecting, processing, and distributing whole blood or plasma separated from whole blood. However, the regulations made under the Food and Drugs Act, a Federal statute, apply to blood establishments who, as distributors of blood, fall within the general definition of a "manufacturer'. Manufacturers are required to establish and follow procedures that will preclude, or at least minimize, the collection of infected source materials and reduce the probability or extent of contamination of any pooled biological materials.

China

Under the blood donation law: "中華人民共和國獻血法", the Ministry of Health has issued regulations in 1998, "血站管理辦法", which prescribe the criteria for eligible blood donors ("獻血者健康檢查標準").